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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/581,718 | 06/22/2006 | Denis Claude Roy | 1032256-000056 | 8573 |

34263 7590 01/06/2011

O"Melveny & Myers LLP
IP&T Calendar Department LA-13-A7
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| EXAMINER | |
|---|---|
| JUEDES, AMY E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 01/06/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/581,718 | ROY ET AL. | |
| | Examiner | Art Unit | |
| | AMY E. JUEDES | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *49-52 and 83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-52 and 83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's amendment and remarks, filed 10/29/10, are acknowledged.
Claims 53-82 have been cancelled.
Claims 49 and 83 have been amended.
Claims 49-52 and 83 are pending and are under examination.

2. The rejection of the claims under 35 U.S.C 102 and 103 as being anticipated/obvious over WO 01/24824 in view of Golnnick et al. is withdrawn in view of Applicant's amendment to recite a vaccine comprising "antigen presenting cells that have not been PDT-treated".

3. The information disclosure statement, filed on 10/29/10, is acknowledged. However, reference 3 has been lined through since it is not a valid U.S. Patent publication number.

4. Claim 49-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/24824 in view of Lambert et al., 2001.

As set forth previously, WO 01/24824 teaches a composition comprising an autologous cell vaccine for treatment of autoimmune disease in a patient, said composition comprising PDT treated peripheral blood cells (see pages 11-12 and 18-19, in particular). WO 01/24824 teaches that said blood cells comprise autoreactive cells (see page 18, in particular). WO 01/24824 teaches a photactivatable compound of formula I of the instant application. WO 01/24824 teaches activating said compound with light of a wavelength of around 512 nm (see pages 10-11 and 21, in particular). WO 01/24824 teaches that the compound/light treatment of the cell compositions results in destruction (i.e. death) of cells in the composition (see page 10 in particular). WO 01/24824 teaches that the vaccine can induce immunomodulation through enhanced presentation of antigens from the apoptotic/dead immunoreactive (i.e. autoreactive) cells in the composition (see page 19, in particular).

WO 01/24824 does not teach the immunologic vaccine further comprising non-PDT treated APCs.

Lambert et al. teach that dendritic cells loaded with apoptotic or lysed cells induce a more potent immune response than the cells or cellular antigen alone.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a non-PDT treated dendritic cell, as taught by Lambert et al., in the immunologic vaccine comprising dead/apoptotic cellular material as taught by WO 01/24824. One of ordinary skill in the art at the time the invention

was made would have been motivated to include a dendritic cell in the immunologic vaccine in order to enhance the presentation of the dead cellular material of the vaccine and induce an enhanced immune response to the cellular material.

Applicant's arguments filed 10/29/10 have been fully considered, but they are not persuasive.

Applicant argues that WO 01/24824 teaches away from adding antigen presenting cells to the immunologic vaccine, since the reference teaches that PDT treatment eliminates antigen presenting B cells and dendritic cells.

WO 01/248245 on page 17 generally describes the cells sensitive to PDT treatment as including activated T cells, B cells, and potentially dendritic cells and states that PDT treatment can be used to eliminate immune cells that could be involved in immune disorders. However, on pages 18-19, WO 01/24824 goes on to specify that in the context of autoimmune disease, PDT treatment is useful for eliminating autoreactive immune cells (i.e. T cells or B cells) before autologous cell transplantation is performed. WO 01/24824 also teaches that one of the mechanisms by which such a therapy functions is to induce immunomodulation through enhanced presentation of antigens from these autoreactive cells after injecting the apoptotic autoreactive cells (see page 19, in particular). It is well established that dendritic cells function to present antigens, and the ordinary artisan would have been motivated to include dendritic cells in the compositions to enhance presentation of the apoptotic cells, as taught by Lambert et al. Thus, while WO 01/24824 may generally describe the potential depletion of dendritic cells for treating certain immune disorders, the reference also specifically teaches the usefulness of inducing apoptosis of autoreactive immune cells for presentation by antigen presenting cells for inducing immunomodulation as a means to treat autoimmune disease. This would suggest that the presence of antigen presenting cells is crucial for inducing immunomodulation, and the ordinary artisan would be motivated to add non-PDT treated dendritic cells (i.e. viable dendritic cells) to ensure adequate presentation of the apoptotic autoreactive cells for treating autoimmune disease. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art.

5. The following are new grounds of rejection necessitated by Applicant's amendment.

6. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/24824 and Lambert et al., 2001, as applied to claims 49-52 above, and further in view of Gollnick et al., March 2003 (of record).

The combined teachings of WO 01/24824 and Lambert et al. are discussed above.

They do not teach a vaccine consisting of a supernatant of the PDT treated cells.

Gollnick et al. teach a lysate of PDT treated cells can be used as an immunologic vaccine to induce an immune response against antigens from the cells (see page 1604, in particular). Gollnick et al. teach producing the cell lysate by treating the cells with photoforin (i.e. a photoactivatable compound) activating the cells with light (see page 1604, in particular), and separating and collecting the cell supernatant.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use an immunologic vaccine consisting of the supernatant of PDT treated cells, as taught by Gollnick et al., using the PDT treated autoreactive peripheral blood cells of WO 01/24824. The ordinary artisan would have been motivated to do so, and have a reasonable expectation of success, since Gollnick et al. teach that said supernatants act as potent immunologic vaccines, and WO 01/24824 teaches that the presentation of antigens from autoreactive PDT treated cell vaccine is effective for treatment of autoimmune disorders. Furthermore, Lambert et al. teach that dendritic cells can readily present cell lysates (see page 234, in particular), and the ordinary artisan would be motivated and have a reasonable expectation of success in including dendritic cells in the vaccine compositions to ensure adequate presentation of the cell lysate antigens.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes

Patent Examiner

Technology Center 1600

/Amy E. Juedes/

Primary Examiner, Art Unit 1644